

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



551058

(43) International Publication Date
21 July 2005 (21.07.2005)

PCT

(10) International Publication Number
WO 2005/065685 A1

(51) International Patent Classification⁷: **A61K 31/43, 9/26**

(21) International Application Number:
PCT/IN2005/000005

(22) International Filing Date: 5 January 2005 (05.01.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
22/DEL/2004 6 January 2004 (06.01.2004) IN
27/DEL/2004 6 January 2004 (06.01.2004) IN

(71) Applicant (for all designated States except US):
PANACEA BIOTEC LTD. [IN/IN]; B-1 Extn./A-27,
Mohan Co-operative Industrial Estate, Mathura Road,
New Delhi 110 044 (IN).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **JAIN, Rajesh**
[IN/IN]; Panacea Biotec Ltd., B-1 Extn./A-27, Mohan
Co-operative Industrial Estate, Mathura Road, New
Delhi 110 044 (IN). **JINDAL, Kour, Chand** [IN/IN];
Panacea Biotec Ltd., B-1 Extn./A-27, Mohan Co-operative
Industrial Estate, Mathura Road, New Delhi 110 044
(IN). **SINGH, Sukhjeet** [IN/IN]; Panacea Biotec Ltd.,
B-1 Extn./A-27, Mohan Co-operative Industrial Estate,
Mathura Road, New Delhi 110 044 (IN).

(74) Agent: **GUPTHA, Bhartee**; Panacea Biotec Limited,
B-1 Extn., A-27, Mohan Co-operative Industrial Estate,
Mathura Road, New Delhi 110 044 (IN).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,

MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO,
SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,
GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii)) for the following designations AE,
AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ,
CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE,
EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS,
JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA,
MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM,
PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY,
TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA,
ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ,
NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM,
AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT,
BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR,
HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK,
TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG)
- of inventorship (Rule 4.17(iv)) for US only

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION COMPRISING AN ACID-INSOLUBLE AND A BIOADHESIVE POLYMER

(57) Abstract: Rapidly disintegrating oral controlled release pharmaceutical compositions and process for preparation of such compositions are provided. The compositions preferably comprise antibiotic(s) as active ingredient, more preferably amoxicillin either alone or in combination with other antibiotic(s). The controlled release compositions comprise at least one active ingredient, and a polymer system comprising of at least two polymers which retard the release of the active ingredient in the stomach while providing rapid release of the said active ingredient in the alkaline contents of small intestine, optionally with other pharmaceutically acceptable excipients. The compositions provide therapeutically effective levels of the active ingredient for extended periods of time, and possess bioadhesive properties.

WO 2005/065685 A1